Proposed Registration Decision PRD2023-02

GS-omega/kappa-Hxtx-Hv1a, SPEAR T and SPEAR-LEP

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Overview

Proposed registration decision for GS-omega/kappa-Hxtx-Hv1a

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is proposing registration for the sale and use of VST-006335 MP Technical, SPEAR T and SPEAR-LEP, containing the technical grade active ingredient GS-omega/kappa-Hxtx-Hv1a, to control or suppress thrips, whiteflies, mites, spotted-wing drosophila and listed Lepidopteran pests on various listed field and greenhouse crops and cannabis.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of GS-omega/kappa-Hxtx-Hv1a and SPEAR T and SPEAR-LEP.

What does Health Canada consider when making a registration decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to individuals and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the Health Canada regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides section of Canada.ca.

Before making a final registration decision on GS-omega/kappa-Hxtx-Hv1a, SPEAR T and SPEAR-LEP, Health Canada's PMRA will consider any comments received from the public in

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act.*

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

response to this consultation document.[3] Health Canada will then publish a Registration Decision[4] on GS-omega/kappa-Hxtx-Hv1a, SPEAR T and SPEAR-LEP, which will include the decision, the reasons for it, a summary of comments received on the proposed registration decision and Health Canada's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What is GS-omega/kappa-Hxtx-Hv1a?

GS-omega/kappa-Hxtx-Hv1a is a peptide derived from the venom of a species of Australian funnel spider (*Hadronyche versuta*). The active ingredient affects the insect nervous system.

Health considerations

Can approved uses of GS-omega/kappa-Hxtx-Hv1a affect human health?

GS-omega/kappa-Hxtx-Hv1a is unlikely to affect human health when used according to label directions.

Potential exposure to GS-omega/kappa-Hxtx-Hv1a may occur through the diet (food and water) or when handling or applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). As such, sex and gender are taken into account in the risk assessment. Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed.

In laboratory animals, VST-006335 MP Technical is considered to be of low acute toxicity by the oral, dermal, and inhalation routes, minimally irritating to the eyes, mildly irritating to the skin, and not a dermal sensitizer.

Short-term oral toxicity testing, prenatal developmental toxicity testing, and genotoxicity/mutagenicity testing on GS-omega/kappa-Hxtx-Hv1a were also assessed. Animals given repeated high doses of GS-omega/kappa-Hxtx-Hv1a exhibited changes in clinical chemistry parameters.

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3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

There was no indication that the young were more sensitive than the adult animal. GS-omega/kappa-Hxtx-Hv1a was not mutagenic in a reverse gene mutation assay in bacteria and was not clastogenic in an in vitro mammalian cell gene mutation assay.

The end-use product, SPEAR T, is considered to be of low acute toxicity by the oral, dermal and inhalation routes, minimally irritating to the eyes, mildly irritating to the skin and not a dermal sensitizer. The toxicological profile of SPEAR-LEP is equivalent to the toxicological profile of SPEAR T.

Residues in water and food

Dietary risks from food and water are acceptable.

Residues of GS-omega/kappa-Hxtx-Hv1a on treated crops are possible at the time of harvest. Due to its low toxicity profile, and the low application rate, consumer exposure to GS-omega/kappa-Hxtx-Hv1a present in SPEAR T and SPEAR-LEP is not expected to pose a health risk when the end-use products are applied as directed by the label. Similarly, the likelihood of GS-omega/kappa-Hxtx-Hv1a residues in drinking water will be low. Consequently, health risks are acceptable for all segments of the population, including infants, children, adults and seniors.

Risks in residential and other non-occupational environments

Estimated risk for residential and other non-occupational exposure is acceptable.

SPEAR T and SPEAR-LEP are proposed as commercial insecticide/acaricide end-use products. There are no residential uses proposed for SPEAR T and SPEAR-LEP. Both products are proposed for use outdoors on field grown food crops, such as fruit (orchard and field crops) and vegetable crops, whereas SPEAR T is also proposed for use indoors on greenhouse-grown food crops, ornamentals, and cannabis grown in greenhouses or other enclosed growing structures. The product labels will include measures to prevent bystander exposure such as reducing spray drift, and restricting access to the treated area until sprays have dried. Residential and non-occupational exposure to SPEAR T and SPEAR-LEP is expected to be low when label directions are observed. Consequently, the risk to residents and the general public is acceptable.

Occupational risks from handling SPEAR T and SPEAR-LEP

Occupational risks are acceptable when SPEAR T and SPEAR-LEP are used according to the label directions, which include protective measures.

Workers handling SPEAR T and SPEAR-LEP can come into direct contact with GS-omega/kappa-Hxtx-Hv1a through inhalation and contact with skin during mixing, loading, application, clean-up and repair.

To protect workers from exposure to SPEAR T and SPEAR-LEP, the labels require workers to wear long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during mixing, loading, application, clean-up and repair. Gloves are not required during application within a closed cab.

For applications using airblast equipment, workers must wear coveralls with a hood over long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes, and a respirator with a NIOSH-approved organic-vapour-removing cartridge with a prefilter approved for pesticides or a NIOSH-approved canister approved for pesticides.

A restricted-entry interval (REI) of 4 hours, or until sprays have dried, is prescribed for all uses. If early entry is necessary during the restricted-entry interval, workers must wear the appropriate personal protective equipment (PPE) as specified by the method of application.

The occupational risks are acceptable when the precautionary statements on the label are observed.

Environmental considerations

What happens when GS-omega/kappa-Hxtx-Hv1a is introduced into the environment?

VST-006335 MP Technical contains the active substance, GS-omega/kappa-Hxtx-Hv1a. GS-omega/kappa-Hxtx-Hv1a is not expected to pose a risk to the environment when used according to product label instructions to control insect pests in greenhouse vegetable crops and fruits, outdoor fruit trees, greenhouse ornamentals, and cannabis produced commercially indoors or in greenhouses.

GS-omega/kappa-Hxtx-Hv1a is an amino acid peptide that will degrade rapidly through microbial processes and is non-persistent in terrestrial and aquatic environments. GS-omega/kappa-Hxtx-Hv1a is not expected to accumulate in plants and animals nor leach through the soil or move up into the surrounding air from where it is applied.

GS-omega/kappa-Hxtx-Hv1a does not pose a risk to birds, mammals, pollinators (bees), beneficial arthropods, terrestrial plants, fish, amphibians, aquatic invertebrates or aquatic plants.

Value considerations

What is the value of SPEAR T and SPEAR-LEP?

SPEAR T is intended for use on several agricultural field and greenhouse crops and cannabis to manage thrips, whiteflies, spider mites, and spotted wing drosophila. SPEAR-LEP is intended for use on fruit and vegetable crops to control Lepidopteran pests.

SPEAR T and SPEAR-LEP are to be used in alternation with other registered insecticides as part of an Integrated Pest Management program. SPEAR-LEP is mixed with a tank mix partner containing *Bacillus thuringiensis* (Bt) subspecies *kurstaki* or *aizawai*. It is thought that the activity of Bt on the insect gut assists the mode of action of SPEAR-LEP.

Measures to minimize risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the labels of VST-006335 MP Technical, SPEAR T and SPEAR-LEP to address the potential risks identified in this assessment are as follows.

Key risk-reduction measures - Human health

The hazard signal words “CAUTION- SKIN IRRITANT” are required on the principal display panel of the VST-006335 MP Technical, SPEAR T, and SPEAR-LEP labels. Standard precautionary statements are also required on the labels to inform of the potential to cause skin irritation and to avoid contact with skin, eyes, or clothing.

Workers are required to wear long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes during handling, mixing, loading, application, clean-up and repair. Gloves are not required during application within a closed cab.

During airblast applications, workers must wear coveralls with a hood over long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes and a respirator with a NIOSH-approved organic-vapour-removing cartridge with a prefilter approved for pesticides or a NIOSH-approved canister approved for pesticides, during mixing, loading, application, clean-up and repair.

There will be a restricted-entry interval of 4 hours, or until sprays have dried. If early entry is necessary during the restricted-entry interval, workers must wear the appropriate PPE as specified for the method of application.

To limit bystander exposure, both end-use product labels require drift statements.

Key risk-reduction measures - Environment

None required following risk assessment.

Next steps

Before making a final registration decision on GS-omega/kappa-Hxtx-Hv1a, SPEAR T and SPEAR-LEP, Health Canada's PMRA will consider any comments received from the public in response to this consultation document. Health Canada will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). Health Canada will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed decision and Health Canada's response to these comments.

Other information

When the Health Canada makes its registration decision, it will publish a Registration Decision on GS-omega/kappa-Hxtx-Hv1a, SPEAR T and SPEAR-LEP (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room. For more information, please contact the PMRA's Pest Management Information Service.

Science evaluation

GS-omega/kappa-Hxtx-Hv1a, SPEAR T and SPEAR-LEP

1.0 The active ingredient, its properties and uses

1.1 Identity of the active ingredient

Active substance	GS-omega/kappa-Hxtx-Hv1a (peptide)
Function	Acaricide, Insecticide
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	Not applicable
2. Chemical Abstracts Service (CAS)	Not applicable
CAS number	2307677-15-0
Molecular formula	Not applicable
Molecular weight	4.565 kDa
Structural formula	Not applicable
Purity of the active ingredient	3%

1.2 Physical and chemical properties of the active ingredient and end-use products

Technical product—VST-006335 MP technical

Property	Result
Colour and physical state	Very dark orange to red-brown, aqueous solution
Odour	Sour, yeasty, phenolic, medicinal, beer
Melting range	Not applicable; the product is a liquid at room temperature.
Density	1.03–1.04 g/mL
Ultraviolet (UV)-visible spectrum	Three absorbance maxima at approximately 205, 220/221, and 260/273 nm were observed in all three pH conditions (acidic, neutral, basic).
Miscibility	Miscible in water
Viscosity	5.2–6.3 cP

Property	Result
pH of 1% dispersion in water	4.75–4.78
Stability (temperature, metal)	Stable under accelerated (54°C for 2 weeks) conditions. Degradation observed when exposed to iron, iron acetate, and aluminum acetate at ambient temperature and 54°C.

End-use products— SPEAR T and SPEAR-LEP

Property	Result
Colour	Brown
Odour	Sweet yeast
Physical State	Liquid
Formulation Type	Solution (SN)
Label concentration	2% GS-omega/kappa-Hxtx-Hv1a
Container material and description	Plastic jug or tote, 0.1 L to bulk
Density	1.030 g/mL
Viscosity	1.6 centistokes at 20°C 1.0 centistokes at 40°C
pH of 1% dispersion in water	5.17
Storage stability	Stable in plastic containers under accelerated (54°C for 2 weeks) conditions.
Corrosion Characteristics	No corrosion was observed to the plastic containers after storage for 14 days at 54°C

1.3 Directions for use

SPEAR T: For indoor applications, mix 2–3 litres of SPEAR T with water to a total volume of 100 litres to prepare a 2–3% product solution. For outdoor applications against spotted-wing drosophila, apply 9.4–28 L of SPEAR T per hectare. Use a spreader/sticker or non-ionic surfactant at 0.125% v/v. Repeat applications at 3-day to 10-day intervals. Under heavy pest pressure conditions, shorten the spray interval, use a higher rate, and/or increase spray volume to improve spray coverage. Do not make more than three consecutive applications of SPEAR T and do not make more than six applications per crop. Do not spray to run off.

SPEAR-LEP: Apply SPEAR-LEP at 1.2–2.3 L/ha in a tank mix with the low labelled rate of a *Bacillus thuringiensis* (Bt) product containing the subspecies *kurstaki* (Btk) or the subspecies *aizawai* (Bta). Use a spreader/sticker or non-ionic surfactant at 0.125% v/v. Repeat applications at 3-day to 10-day-intervals depending upon plant growth rate, pest activity and other factors. Under heavy pest pressure conditions, use the shorter spray interval, the higher rate, and/or increase spray volume to improve spray coverage. Do not make more than three consecutive applications of SPEAR-LEP plus Bt and do not make more than six applications per year.

1.4 Mode of action

GS-omega/kappa-Hxtx-Hv1a is a peptide produced recombinantly, originally derived from the venom of various spider species of the east coast of Australia. The active ingredient reaches target sites in the nervous system by diffusing into the hemocoel via spiracles and is specific to ion channels and nicotinic acetylcholine receptors (nAChRs) in the insect nervous system. This mode of action is classified as a Group 32 insecticide by the Insecticide Resistance Action Committee (IRAC).

2.0 Methods of analysis

2.1 Methods for analysis of the active ingredient

The methods provided for the analysis of the active ingredient in the technical product have been validated and assessed to be acceptable.

2.2 Method for formulation analysis

The method provided for the analysis of the active ingredient in the formulations have been validated and assessed to be acceptable for use as an enforcement analytical method.

2.3 Methods for residue analysis

No methods are required to quantify residues of GS-omega/kappa-Hxtx-Hv1a due to its low toxicity (see Section 3.0).

2.4 Methods for determination of relevant impurities in the manufactured material

The quality assurance procedures used to limit contaminating microorganisms during the manufacture of VST-006335 MP Technical are acceptable. These procedures include sterilization of all equipment and media as well as frequent sampling of the stock culture and production batches for purity and contamination.

The absence of human pathogens and below-threshold levels of contaminating microorganisms were shown in the microbial screening of batches VST-006335 MP Technical using standard methods for detecting and enumerating microbial contaminants of concern. All batches of VST-006335 MP Technical conform to the limits set out in the Organisation for Economic Co-operation and Development (OECD) issue paper on microbial contaminants for microbial pest control products [ENV/JM/MONO(2011)43] and demonstrate absence of the yeast production strain in 1 g or mL.

3.0 Impact on human and animal health

3.1 Toxicology summary

A detailed review of toxicology information was conducted in support of the technical grade active ingredient (TGAI), VST-006335 MP Technical, and the end-use products, SPEAR T and SPEAR-LEP. The data package for VST-006335 MP Technical, SPEAR T, and SPEAR-LEP is considered acceptable (Appendix I, Tables 1–2) to assess the toxic effects that may result from exposure to GS-omega/kappa-Hxtx-Hv1a.

The data package consisted of acute toxicity studies (acute oral, dermal and inhalation toxicity, eye and skin irritation, and dermal sensitization), short-term oral toxicity, prenatal developmental toxicity, in vitro bacterial gene mutation and in vitro mammalian gene mutation studies in support of VST-006335 MP Technical, as well as acute toxicity studies (acute oral and dermal toxicity, and dermal sensitization) for SPEAR T. The test substances used in studies submitted to support the TGAI contained the active ingredient GS-omega/kappa-Hxtx-Hv1a at concentrations ranging from 26.9 to 47.4% w/w (see Appendix I, Table 1). The test substances were all considered acceptable as surrogates to evaluate the toxicology profile of the TGAI, VST-006335 MP Technical containing 3% w/w GS-omega/kappa-Hxtx-Hv1a.

VST-006335 MP Technical is of low acute toxicity by the oral, dermal, and inhalation routes, minimally irritating to the eyes, mildly irritating to the skin, and not a dermal sensitizer.

In a 90 day oral (gavage) toxicity study in rats, treatment-related effects on serum chemistry and thyroid hormone parameters were observed at the lowest observable adverse effects level (LOAEL) of 500 mg a.i./kg/day. The no observable adverse effects level (NOAEL) was 125 mg a.i./kg/day.

In an oral (gavage) prenatal developmental toxicity study in rats, there were no treatment-related effects and no evidence of sensitivity of the young. The maternal and developmental NOAEL was >719.8 mg a.i./kg/day, the highest dose tested.

GS-omega/kappa-Hxtx-Hv1a was not mutagenic in a reverse gene mutation assay in bacteria and was not clastogenic in an in vitro mammalian cell gene mutation assay.

A rationale to waive acute inhalation toxicity, primary eye irritation, and primary dermal irritation testing for SPEAR T, based on testing conducted with concentrated forms of VST-006335 MP Technical, was considered acceptable. SPEAR T is of low acute toxicity by the oral, dermal, and inhalation routes, minimally irritating to the eyes, mildly irritating to the skin, and not a dermal sensitizer. The toxicological profile of SPEAR-LEP is equivalent to the toxicological profile of SPEAR T.

3.2 Dermal absorption

No information was provided on dermal absorption of GS-omega/kappa-Hxtx-Hv1a. Because the surface of GS-omega/kappa-Hxtx-Hv1a is covered in hydrophilic residues, the compound is highly soluble in water, and thus dermal absorption is expected to be low.

3.3 Occupational, residential and bystander exposure and risk assessment

3.3.1 Use description

SPEAR T and SPEAR-LEP are both proposed for registration as commercial insecticide/acaricide end-use products. Both products will be used outdoors on field grown food crops, such as fruit (orchard and field crops) and vegetable crops. SPEAR T will also be used indoors on greenhouse food crops and ornamentals, as well as on cannabis grown in greenhouses or other enclosed growing structures.

The products are liquid formulations which are mixed with water and applied as a foliar spray using conventional ground equipment such as boom sprayers, high- and low-volume sprayers, or by airblast. SPEAR-LEP is applied outdoors at 1.2-2.3 L/ha in a tank mix with the low labelled rate of a registered *Bacillus thuringiensis* product. The minimum spray volume for orchard crops is 470 L/ha and is 187 L/ha for other outdoor crops. Outdoor applications of SPEAR T are made at a rate of 9.4-28 L/ha. The minimum spray volume is 470 L/ha for orchard crops and 187 L/ha for other outdoor crops. When used indoors, SPEAR T is applied as a 2–3% product solution, with enough volume to achieve full coverage of the target crop.

Both products have re-application intervals of 3–10 days, with no more than three consecutive applications, and a maximum of six applications per crop. The products are not to be sprayed to run off.

3.3.2 Occupational exposure and risk assessment

3.3.2.1 Mixer, loader, and applicator exposure and risk assessment

When use according to label directions, occupational exposure to SPEAR T and SPEAR-LEP is characterized as short- and intermediate-term in duration. Occupational exposure is expected to occur primarily by the inhalation and dermal routes during handling, mixing, loading, and application. During clean-up and repair, occupational exposure would be primarily by the dermal route. Ocular exposure is expected to be minimal.

To protect workers from exposure to SPEAR T and SPEAR-LEP during handling, mixing, loading or applying the products by ground application equipment, workers are required to wear long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes. Gloves are not required during application within a closed cab.

Occupational exposure by the dermal and inhalation routes is highest when the end-use products are applied by airblast. Due to the microbial origin of the formulation, in order to limit occupational exposure during airblast application, workers must wear coveralls with a hood over long-sleeved shirt, long pants, chemical-resistant gloves, socks and shoes, and a respirator with a NIOSH-approved organic-vapour-removing cartridge with a prefilter approved for pesticides or a NIOSH-approved canister approved for pesticides.

Precautionary statements on the end-use product labels, such as the wearing of PPE, aimed at mitigating exposure are adequate to protect individuals from any risk due to occupational exposure. Overall, occupational risks to workers are acceptable when the precautionary statements on the labels are followed which include PPE.

3.3.2.2 Postapplication exposure and risk assessment

There is a potential for post-application exposure to workers re-entering areas treated with SPEAR T and SPEAR-LEP. Given the nature of the post-application activities typically performed (for example, scouting, harvesting, thinning and pruning), dermal contact with treated plants is possible. Workers must remain out of the treated area for 4 hours, or until sprays have dried. If early entry is required, workers must wear the appropriate PPE as specified by the application method.

Precautionary (for example, wearing of PPE) statements on the end-use product labels aimed at mitigating exposure are adequate to protect workers from risk due to post-application exposure. Consequently, the risks to workers due to post-application exposure are acceptable.

3.3.3 Residential and bystander exposure and risk assessment

There are no residential uses for SPEAR T and SPEAR-LEP. The commercial use of SPEAR T and SPEAR-LEP, both indoor and outdoor, may result in residential bystander exposure due to drift.

Residential bystander exposure from commercial use will be mitigated by the inclusion of a spray drift statement on the label advising against application to areas of human habitation unless consideration has been given to the wind speed, wind direction, temperature inversions, application equipment, and sprayer settings.

Consequently, the health risks to bystanders and individuals in residential areas to SPEAR T and SPEAR-LEP are considered acceptable.

3.4 Dietary exposure assessment

3.4.1 Food

While dietary exposure to GS-omega/kappa-Hxtx-Hv1a may occur through consumption of treated crops, residues are expected to be low based on the level of the active ingredient in the products and the low application rates. Furthermore, GS-omega/kappa-Hxtx-Hv1a has a low toxicity profile. Consequently, when the end-use products are applied as directed by the label, the health risk is acceptable for the general population, including infants and children, and domestic animals.

Similarly, when SPEAR T is applied to cannabis grown in greenhouses and enclosed structures, risk from consumer exposure to cannabis treated with SPEAR T is acceptable due to the low toxicity profile and the low application rate.

3.4.2 Drinking water

Dietary exposure from drinking water is expected to be low as the label has the necessary mitigative measures to limit contamination of drinking water from the proposed uses of GS-omega/kappa-Hxtx-Hv1a.

Health risks from residues of GS-omega/kappa-Hxtx-Hv1a in drinking water are acceptable due to the low toxicity profile and limited exposure following application of SPEAR T and SPEAR-LEP.

3.4.3 Acute and chronic dietary risks for sensitive subpopulations

As noted above, when the end-use products are applied as directed by the label, the health risk is acceptable for the general population, including infants and children, and domestic animals.

3.5 Aggregate exposure and risk

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal and inhalation).

In an aggregate risk assessment, the combined potential risk associated with food, drinking water and various residential exposure pathways is assessed. A major consideration is the likelihood of co-occurrence of exposures. Additionally, only exposures from routes that share common toxicological endpoints can be aggregated.

GS-omega/kappa-Hxtx-Hv1a is considered to be of low toxicity by the oral, dermal, and inhalation routes, and the end-use products will not be applied near, or to, drinking water. Furthermore, non-occupational exposure will be low when SPEAR T and SPEAR-LEP are used as directed on the label. When the end-use products are used as labelled, there is reasonable certainty that no harm will result from aggregate exposure of residues of GS-omega/kappa-Hxtx-Hv1a.

3.6 Cumulative assessment

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. Accordingly, assessments of potential common mechanisms of toxicity with other pesticides were undertaken.

For the current evaluation, PMRA did not identify information indicating that GS-omega/kappa-Hxtx-Hv1a shares a common mechanism of toxicity with other registered pest control products. Therefore, there is no requirement for a cumulative health risk assessment at this time.

3.7 Maximum residue limits (MRLs)

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether dietary risks are acceptable from the consumption of foods treated with the pesticide when used according to the supported label directions. If acceptable, this means food containing that amount of residue is safe to eat, and maximum residue limits (MRLs) may be proposed. MRLs are the maximum amount of pesticide residue legally permitted to remain in/on food sold in Canada and are specified under the *Pest Control Products Act* for the purposes of the adulteration provision of the *Food and Drugs Act.*

Dietary risk from the proposed use of GS-omega/kappa-Hxtx-Hv1a is acceptable, given the low toxicity profile of GS-omega/kappa-Hxtx-Hv1a and the low application rates. Consequently, the specification of MRLs, under the *Pest Control Products Act*, will not be required for GS-omega/kappa-Hxtx-Hv1a.

3.8 Health incident reports

GS-omega/kappa-Hxtx-Hv1a is a new active ingredient pending registration for use in Canada, and as of 12 October 2022, no human or domestic animal incident reports had been submitted to the PMRA.

4.0 Impact on the environment

4.1 Fate and behaviour in the environment

GS-omega/kappa-Hxtx-Hv1a is a peptide that will break down rapidly in the environment into common amino acids and is reported to have a half-life of approximately 4 days or less in the field. Hence, GS-omega/kappa-Hxtx-Hv1a would be non-persistent in terrestrial and aquatic habitats and is not expected to bioaccumulate. In addition, GS-omega/kappa-Hxtx-Hv1a is not expected to leach through the soil or move up into the atmosphere from where it is applied.

4.2 Environmental risk characterization

Characterization of the environmental risk is applicable for the outdoor use of GS-omega/kappa-Hxtx-Hv1a on fruit and vegetable crops. The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing estimated environmental concentrations (EECs) in various media (food, water, soil and air) with concentrations at which adverse effects occur.

The EECs are estimated using standard models which take into consideration the application rate(s), the number of applications per season, the application intervals, chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. A summary of the EECs is presented in Appendix I, Tables 3–5.

Ecotoxicology information includes acute and chronic toxicity data for organisms (invertebrates, vertebrates and plants) from both terrestrial and aquatic habitats. Effects metrics are toxicity endpoints that have been adjusted by an uncertainty factor to account for potential differences in species sensitivity as well as varying protection goals (i.e. protection at the community, population, or individual level). A summary of the terrestrial and aquatic endpoints available and effects metrics used in the risk assessment are presented in Appendix I, Table 6.

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the EEC by an appropriate effects metric, and then compared to the level of concern (LOC). If the screening level risk quotient is below the LOC, the risk is considered negligible and no further risk characterization is necessary. If the screening level RQ is equal to or greater than the LOC, further characterization of risk is conducted by taking into consideration more realistic exposure scenarios and effects metrics. A summary of the RQs for each taxonomic group is provided in Appendix I, Table 7 and 8.

4.2.1 Risks to terrestrial organisms

Screening level risk

At the screening level, the risks from exposure to GS-omega/kappa-Hxtx-Hv1a are acceptable for beneficial arthropods, pollinators (bees), and small mammals as the LOC was not exceeded. For vascular plants and birds, risks of concern are not expected as no effects were observed at the highest tested exposure levels (Appendix I, Tables 7 and 8).

4.2.2 Risks to aquatic organisms

Screening level risk

At the screening level, the risks from exposure to GS-omega/kappa-Hxtx-Hv1a are acceptable as the LOC was not exceeded for amphibians, fish and aquatic invertebrates (Appendix I, Table 7).

No toxicity data were available for freshwater and marine algae and aquatic vascular plants. The registrant provided a rationale to waive these data based on the non-phytotoxic nature of GS-omega/kappa-Hxtx-Hv1a (PMRA #3105677).

Phytotoxicity was not exhibited in terrestrial vascular plant studies and no phytotoxic effects were evident in numerous field trials with several crop species. On this basis, it is not expected that phytotoxic effects would be evident in algae or aquatic vascular plants, hence, the risk of exposure to GS-omega/kappa-Hxtx-Hv1a is acceptable.

Overall conclusion about potential risks to non-target terrestrial and aquatic organisms

Based on the proposed uses of SPEAR-LEP and SPEAR T, it is unlikely that aquatic and terrestrial organisms would be exposed to environmental concentrations of GS-omega/kappa-hxtx-hv1a that would result in adverse effects. The environmental risk is therefore, acceptable for these products when used in accordance with label directions.

4.2.3 Environment incident reports

As of 12 October 2022, no environmental incidents involving GS-omega/kappa-Hxtx-Hv1a have been submitted to the PMRA.

5.0 Value

A total of 21 efficacy trials and scientific rationales were reviewed to support the use claims against insect pests of fruit crops, vegetable crops, greenhouse ornamentals, and cannabis. The value information indicated that treatment with SPEAR T or with SPEAR-LEP tank mixed with Bt products controls or suppresses important insect pests of the labeled crops. A review of the submitted value information indicated that the data were sufficient to support the claims.

The insects and mites on the SPEAR T and SPEAR-LEP labels can cause yield and quality losses to crops resulting in economic losses. The quality of the fruits, vegetables, or cannabis can be reduced to a point of being unmarketable, which can lead to additional losses of revenue. The addition of SPEAR T and SPEAR-LEP to the insecticide rotation program for agricultural crops or cannabis also allows for a more sustainable approach to crop production with the option of a non-conventional insecticide. GS-omega/kappa-Hxtx-Hv1a offers growers a new mode of action to help manage resistance development in insects and mites.

6.0 Pest control product policy considerations

6.1 Toxic substances management policy considerations

The *Toxic Substances Management Policy* (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances, i.e., those that meet all four criteria outlined in the policy: persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*. The *Pest Control Products Act* requires that the TSMP be given effect in evaluating the risks of a product.

During the review process, VST-006335 MP Technical was assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has determined that VST-006335 MP Technical does not meet the TSMP Track 1 criteria.

6.2 Formulants and contaminants of health or environmental concern

During the review process, contaminants in the active ingredient as well as formulants and contaminants in the end-use products are compared against Parts 1 and 3 of the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern.*[6] The list is used as described in the PMRA Science Policy Note SPN2020-01[7] and is based on existing policies and regulations, including the *Toxic Substance Management Policy* and *Formulants Policy*,[8] and taking into consideration the *Ozone-Depleting Substances and Halocarbon Alternatives Regulations* under the *Canadian Environmental Protection Act, 1999*, (substances designated under the *Montreal Protocol*).

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5 DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

6 SI/2005-114, last amended on June 24, 2020. See Justice Laws website, Consolidated Regulations, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

7 PMRA's Science Policy Note SPN2020-01, *Policy on the List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under paragraph 43(5)(b) of the New Pest Control Products Act.*

8 DIR2006-02, *Formulants Policy and Implementation Guidance Document.*

The PMRA has reached the following conclusions:

- VST-006335 MP Technical and the end-use products, SPEAR T and SPEAR-LEP, do not contain any formulants or contaminants identified in the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern*.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

7.0 Proposed regulatory decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act*, is proposing registration for the sale and use of VST-006335 MP Technical, SPEAR T and SPEAR-LEP, containing the technical grade active ingredient GS-omega/kappa-Hxtx-Hv1a, to control or supress thrips, whiteflies, mites, spotted-wing drosophila and listed Lepidopteran pests on various listed field and greenhouse crops and cannabis.

An evaluation of available scientific information found that, under the approved conditions of use, the health and environmental risks and the value of the pest control products are acceptable.

List of abbreviations

µg	micrograms
♀	female
♂	male
1/n	exponent for the Freundlich isotherm
a.i.	active ingredient
ADI	acceptable daily intake
ALS	acetolactate synthase
ARfD	acute reference dose
atm	atmosphere
Bt	*Bacillus thuringiensis*
Bta	*Bacillus thuringiensis* subspecies *aizawai*
Btk	*Bacillus thuringiensis* subspecies *kurstaki*
bw	body weight
CAS	Chemical Abstracts Service
cm	centimetres
cm^3	Cubic centimetre(s)
cP	centiPoise
d	Day(s)
DACO	Data code
DF	dry flowable
DIR	Regulatory Directive
DNA	deoxyribonucleic acid
DT_{50}	dissipation time 50% (the dose required to observe a 50% decline in concentration)
DT_{90}	dissipation time 90% (the dose required to observe a 90% decline in concentration)
EC_{25}	effective concentration on 25% of the population
EC_{50}	effective concentration on 50% of the population
EDE	Estimated Dietary Exposure
EEC	Estimated Environmental Concentration
EP	end-use product
EPA	Environmental Protection Agency
ER_{25}	effective rate for 25% of the population
g	gram
g/mL	gram per millilitre
h	Hour(s)
ha	hectare(s)
HDT	highest dose tested
Hg	mercury

HPLC	high performance liquid chromatography
hr	hour
hrs	hours
IRAC	Insecticide Resistance Action Committee
IUPAC	International Union of Pure and Applied Chemistry
K_d	soil-water partition coefficient
kDa	kiloDalton
K_F	Freundlich adsorption coefficient
kg	Kilogram(s)
km	kilometre
K_{oc}	organic-carbon partition coefficient
K_{ow}	*n*–octanol-water partition coefficient
L	litre
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOAEL	lowest observed adverse effect level
LOC	Level Of Concern
LOEC	low observed effect concentration
LOQ	limit of quantitation
LR_{50}	lethal rate 50%
MAS	maximum average score
mg	Milligram(s)
MIS	maximum irritation score (at a specified timepoint)
mL	millilitre
MOE	margin of exposure
MRL	maximum residue limit
MS	mass spectrometry
MW	molecular weight
N/A	not applicable
N/R	not required
nAChRs	nicotinic acetylcholine receptors
NC	not classified
nm	nanometre
NOAEC	No Observed Adverse Effects Concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NOER	no observed effect rate
NZW	New Zealand white
OC	organic carbon content

ºC	degree Celsius
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content
PBI	plantback interval
PHI	preharvest interval
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppm	parts per million
RQ	Risk Quotient
RSD	relative standard deviation
SC	soluble concentrate
SPN	Science Policy Note
$t_{1/2}$	half-life
T3	tri-iodothyronine
T4	thyroxine
TGAI	technical grade active ingredient
TRR	total radioactive residue
TSMP	Toxic Substances Management Policy
UAN	urea ammonium nitrate
UF	uncertainty factor
USEPA	United States Environmental Protection Agency
UV	ultraviolet
v/v	volume per volume dilution
w/w	Weight to weight ratio
wt	Weight

Appendix I Tables and figures

Table 1 Toxicity profile of VST-006335 MP Technical

(Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons)

Study Type/Animal/PMRA #	Study Results
Acute Toxicity Studies	
Acute oral toxicity[1] (up and down) Rat, Sprague-Dawley (♀) PMRA # 3105697	LD_{50} >5000 mg/kg bw (limit test) Low acute toxicity
Acute dermal toxicity[1] Rat, Sprague-Dawley (♂♀) PMRA #3105696	LD_{50} >5000 mg/kg bw (limit test) Low acute toxicity
Acute inhalation toxicity[2] Rat, Sprague-Dawley (♂♀) PMRA #3105695	LC_{50} >2.05 mg/L (limit test) Low acute toxicity
Primary eye irritation[3] Rabbit, New Zealand albino (♀) PMRA # 3105694	MAS (24, 48, & 72 hrs) = 0.22/110 MIS = 8.0/110 at 1 hr Conjunctivae marked by redness, chemosis, and discharge. No signs of irritation at 48 hrs. Minimally irritating
Primary skin irritation[3] Rabbit, New Zealand albino (♂) PMRA # 3105693	MAS (24, 48, and 72 hrs) = 2.0/8 MIS = 3.0/8 at 1 hr Very slight to well-defined erythema and very slight edema was observed in the test animals. All signs of irritation resolved by Day 7. Mildly irritating
Dermal sensitization[1] (Buehler Method) Guinea pig, Hartley albino (♂)	Negative Not a dermal sensitizer

PMRA # 3105692	
Short-Term Toxicity Studies	
90-Day oral toxicity (gavage)[4] Rat, CRL: Sprague-Dawley CD IGS (♂♀) PMRA # 3286618	NOAEL = 125 mg/kg/day of GS-omega/kappa-Hxtx-Hv1a ≥ 500 mg/kg/day:↓ absolute basophil (♂), ↓ chloride (♂),↓ T3 (♂/♀), ↓ TSH (♀) ≥ 1000 mg/kg/day: ↓ aspartate aminotransferase (♂), ↑ glucose (♂), ↓ sodium (♂), hepatic vacuolation (2/10) (♂)
Reproductive/Developmental Toxicity Studies	
Prenatal developmental toxicity[5] Rat, CRL: Sprague-Dawley CD IGS (♀) PMRA # 3358963	**Maternal** NOAEL > 719.8 mg a.i./kg/day **Developmental** NOAEL > 719.8 mg a.i./kg/day **No evidence of sensitivity of the young**
Genotoxicity Studies	
Bacterial reverse mutation assay[4] *Salmonella typhimurium* (TA98, TA100, TA1535, and TA1537) and *Escherichia coli* strain (WP2 uvrA) PMRA # 3286620	Negative
Mammalian cell gene mutation assay[6] Chinese Hamster V79 cells PMRA # 3286621	Negative

[1] Substance tested was VST - 006325 (33.5% GS-omega/kappa-Hxtx-Hv1a)
[2] Substance tested was VST - 006325 (32.0% GS-omega/kappa-Hxtx-Hv1a)
[3] Substance tested was VST - 006325 (33.0% GS-omega/kappa-Hxtx-Hv1a)
[4] Substance tested was VST-6300 (42.8% GS-omega/kappa-Hxtx-Hv1a)
[5] Substance tested was VST-6300 (26.9% GS-omega/kappa-Hxtx-Hv1a)
[6] Substance tested was VST-006300 TEP (47.4% GS-omega/kappa-Hxtx-Hv1a)

Table 2 Toxicity profile of SPEAR T and SPEAR-LEP

(Effects are known or assumed to occur in both sexes unless otherwise noted; in such cases, sex-specific effects are separated by semi-colons)

Study Type/Animal/PMRA #	Study Results
Acute oral toxicity[1] (up and down) Rat, Sprague-Dawley (♀) PMRA # 3105877	LD_{50} > 5000 mg/kg bw (limit test) Low acute toxicity
Acute dermal toxicity[1] Rat, Sprague-Dawley (♂♀) PMRA # 3105878	LD_{50} > 5000 mg/kg bw (limit test) Low acute toxicity
Dermal sensitization[1] (Buehler Method) Guinea pig, Hartley albino (♂) PMRA # 3105879	Negative Not a dermal sensitizer
[1] Substance tested was VST-006340 LC (2.0% w/w GS-omega/kappa-Hxtx-Hv1a)	

Table 3 Screening level EECs: soil and water

Use-pattern / Application	End-use product	Max. single rate (g a.i./ha)	Number of applications	Minimum application interval (d)	Max. cumulaltive rate (g a.i./ha)[a]	EEC in soil (mg a.i./kg soil)[ab]	EEC in water (mg a.i./L)[a]	
							15-cm deep pond	80-cm deep pond
Outdoor fruit trees	SPEAR T	577	6	3	1360.6	0.60	0.91	0.17
Outdoor fruit and vegetable crops	SPEAR-LEP	47.4	6	3	110.8	0.05	0.074	0.014

[a]Based on half-life = 4 days.
[b]EEC in soil assumes a soil bulk density of 1.5 g/cm^3, a soil depth of 15 cm.

Table 4 EECs for Bees

Use-pattern	Max. single rate (kg a.i./ha)	Bee stage	Exposure	Exposure to bee (µg a.i./bee/day)*
SPEAR T				
Outdoor fruit trees	0.577	Adult	Oral acute	16.5
		Adult	Oral chronic	16.5
		Adult	Contact acute	1.4
		Larvae	Oral acute	7.0
SPEAR-LEP				
Outdoor fruit trees and vegetable crops	0.0474	Adult	Oral acute	1.4
		Adult	Oral chronic	1.4
		Adult	Contact acute	0.1
		Larvae	Oral acute	0.6

[a]Based on foliar half-life = 10 days.
*Exposure estimate for bees:
For contact exposure: application rate (kg a.i./ha) x 2.4 µg a.i./bee per kg a.i./ha.
For oral exposure (foliar application): application rate (kg a.i./ha) x 98 µg a.i./g x consumption rate (0.292 g/day for adult bee, 0.124 g/day for larvae)

Table 5 Maximum estimated environmental concentration (EEC) in vegetation and insects after a direct over-spray of GS-omega/kappa-Hxtx-Hv1a

Environmental compartment	Maximum EEC (mg a.i./kg dry wt.)[a]	
	SPEAR T	SPEAR-LEP
Short range grass	1547.2	127.1
Long grass	944.7	77.6
Broadleaf plants	1431.5	117.6
Insects	699.3	57.5
Grain and seeds	108.2	8.9
Fruit	216.5	17.8

[a]Estimates from US EPA nomogram based on data of Hoerger and Kenaga (1972) and Kenaga (1973) and modified according to Fletcher *et al*., (1994).

Table 6 Toxicity to terrestrial and aquatic organisms

Organism	Test	Measurement endpoint	Endpoint value	Degree of toxicity[a]	Uncertainty factor	Effects metric	PMRA#
Terrestrial species							
Invertebrates							
Bee (*Apis mellifera*)	Acute contact (48-h)	LD_{50}	>25 µg a.i./bee	Practically non-toxic	1	>25 µg a.i./bee	3105686
		NOAEC	25 µg a.i./bee No sub-lethal effects	Practically non-toxic	1	25 µg a.i./bee	
	Acute oral (48-h)	LD_{50}	>100 µg a.i./bee	Practically non-toxic	1	>100 µg a.i./bee	3105685
		NOAEC	100 µg a.i./bee No sub-lethal effects	Practically non-toxic	1	100 µg a.i./bee	
	Acute larvae (72-h)	LD_{50}	>68.6 µg a.i./bee	Practically non-toxic	1	>68.6 µg a.i./bee	3105684
Predators							
Green lacewings (*Chrysoperla rufilabris*)	Acute (72-h)	LR_{50}	>20.1 kg a.i./ha. No mortality observed up to 20.1 kg a.i./ha.	N/A	1	>20.1 kg a.i./ha.	3105682
Ladybird beetles (*Hippodamia convergens*)	Acute (72-h)	LR_{50}	>20.1 kg a.i./ha. No mortality observed up to 20.1 kg a.i./ha.	N/A	1	>20.1 kg a.i./ha.	3105683
Parasitoids							
Whitefly Parasitic Wasp (*Eretmocerus eremicus*)	Acute (72-h)	LR_{50}	>20.1 kg a.i./ha. No significant differences	N/A	1	>20.1 kg a.i./ha.	3105681

Organism	Test	Measurement endpoint	Endpoint value	Degree of toxicity[a]	Uncertainty factor	Effects metric	PMRA#
			in mortality at rate of 20.1 kg a.i./ha for EP, VST-006330				
Birds							
Bobwhite Quail (*Colinus virginianus*)	Acute oral (14 day)	LD_{50}	>630 mg a.i./kg- bw No effects were observed at the highest test concentration	Slightly toxic	10	>63.0 mg a.i./kg-bw	3105678
		NOAEC	>630 mg a.i./kg- bw (based on mortality)	N/A	1	>630 mg a.i./kg-bw	
Mammals							
Rat	Acute Oral	LD_{50}	>5000 mg/kg bw (both male and female rats)	Practically non-toxic	10	>500 mg/kg bw	
Vascular plants							
Vascular plants	Vegetative vigour	EC_{25}	>0.90 kg a.i./ha	N/A	1	>0.90 kg a.i./ha	3105676
	Seedling emergence	EC_{25}	>0.90 kg a.i./ha	N/A	1	>0.90 kg a.i./ha	3105675
Freshwater species							
Invertebrates							
Daphnia magna	Acute (48-hour)	EC_{50}	>1000 mg a.i./L	Practically non-toxic	2	>500 mg a.i./L	3105680
		NOEC	>1000 mg a.i./L	Practically non-toxic	1	>1000 mg a.i./L	

Fish							
Rainbow trout (*Oncorhynchus mykiss*)	Acute (96-hour)	LC_{50}	>100 mg a.i./L	Practically non-toxic	10	>10.0 mg a.i./L	3105679
		NOEC	>100 mg a.i./L	Practically non-toxic	1	>100 mg a.i./L	

[a] Atkins et al. (1981) for bees and USEPA classification for others, where applicable; N/A - not applicable.

Table 7 Screening level risks for terrestrial and aquatic organisms other than birds and mammals

Organism	Exposure	Effects metric	EEC	Risk Quotient	LOC Exceeded / Comment
Bee (*Apis mellifera*)	Acute contact	LD_{50} >25 µg a.i./bee	1.4 µg a.i./bee	<0.06	No
	Acute oral	LD_{50} >100 µg a.i./bee	16.5 µg a.i./bee	<0.17	No
		NOAEC = 100 µg a.i./bee	16.5 µg a.i./bee	0.17	No
	72-hour larva	LD_{50} >68.6 µg a.i./bee	7.0 µg a.i./bee	<0.1	No
Green lacewings (*Chrysoperla rufilabris*)	Acute (72-h)	LR_{50} >20.1 kg a.i./ha	2.2 kg a.i./ha	<0.1	No
Ladybird beetles (*Hippodamia convergens*)	Acute (72-h)	LR_{50} >20.1 kg a.i./ha	2.2 kg a.i./ha	<0.1	No
Whitefly Parasitic Wasp (*Eretmocerus eremicus*)	Acute (72-h)	LR_{50} >20.1 kg a.i./ha	2.2 kg a.i./ha	<0.1	No
Terrestrial plants	Acute (14-day)	EC_{25} >0.90 kg a.i./ha	2.2 kg a.i./ha	<2.4	No effects observed on plants at 0.90 kg a.i./ha, thus, a risk is not expected.
Daphnia magna	Acute (48-hour)	EC_{50} >500 mg a.i./L	0.17 mg a.i./L	<0.0003	No
Rainbow trout (*Oncorhynchus mykiss*)	Acute (96-hour)	LC_{50} >10.0 mg a.i./L	0.17 mg a.i./L	<0.02	No
Amphibians	Acute (96-hour)	LC_{50} >10.0 mg a.i./L	0.91 mg a.i./L	0.09	No

Table 8 Screening level risks for birds and mammals

Organism	Effects metric (mg a.i./kg bw/d)	Feeding Guild (food item)	EDE (mg a.i./kg bw)	RQ	LOC Exceeded / Comment
Small Bird (0.02 kg)					
Acute	>63.0	Insectivore	178.3	<2.8	No effects observed at 630 mg a.i./kg- bw, thus, a risk is not expected.
Medium Sized Bird (0.1 kg)					
Acute	>63.0	Insectivore	139.2	<2.2	No effects observed, at 630 mg a.i./kg- bw, thus, a risk is not expected.
Large Sized Bird (1 kg)					
Acute	>63.0	Herbivore (short grass)	89.9	<1.4	No effects observed at 630 mg a.i./kg- bw, thus, a risk is not expected.
Small Mammal (0.015 kg)					
Acute	>500	Insectivore	102.6	0.2	No
Medium Sized Mammal (0.035 kg)					
Acute	>500	Herbivore (short grass)	199.0	0.4	No
Large Sized Mammal (1 kg)					
Acute	>500	Herbivore (short grass)	106.3	0.2	No

Table 9 List of supported uses

SPEAR T

Supported use claim	Use pattern
Vegetables Grown in Greenhouses Cucumber Tomato Peppers Eggplant Vegetable Transplants (Cucumbers, Tomatoes, Peppers and Eggplant) Suppression of Twospotted Spider Mite (*Tetranychus urticae*) Suppression **of** Thrips, including Western Flower Thrips (*Frankliniella occidentalis*) Control **of** Whiteflies, including Sweetpotato Whitefly (*Bemisia tabaci*) and Greenhouse Whitefly (*Trialeurodes vaporariorum*)	For indoor applications, mix 2 - 3 litres of SPEAR T with water to a total volume of 100 litres to prepare a 2 - 3% product solution. For outdoor applications against spotted-wing drosophila, apply 9.4 - 28 L of SPEAR T per hectare. Apply as a foliar spray in enough volume to achieve full coverage of the target crop. Use a spreader/sticker or non-ionic surfactant at 0.125% v/vto enhance the adhesion of SPEAR T to the crop. Repeat applications at 3- to 10-day intervals depending upon plant growth rate, pest activity and climatic factors. Under heavy pest pressure conditions, shorten the spray interval, use a higher rate, and/or increase spray volume to improve spray coverage. Do not make more than three consecutive applications of SPEAR T and do not make more than six applications per crop. Do not spray to run off.
Herbaceous Ornamentals Grown in Greenhouses or in High Tunnels Container grown flowering and foliage annuals and perennials Container or in-ground or soil grown annuals and perennials for cut flowers Suppression **of** Twospotted Spider Mite (*Tetranychus urticae*) Suppression **of** Thrips, including Western Flower Thrips (*Frankliniella occidentalis*) Control **of** Whiteflies, including Sweetpotato Whitefly (*Bemisia tabaci*) and Greenhouse Whitefly (*Trialeurodes vaporariorum*)	

Supported use claim	Use pattern
Blueberry, Cherry and Caneberry (Crop Subgroup 13A) Grown Outdoors or High Tunnels **Suppression of** Spotted-wing drosophila (*Drosophila suzukii*)	
Cannabis Grown in Greenhouses or Produced Commercially Indoors Cannabis (marihuana) produced commercially indoors Suppression **of** Twospotted Spider Mite (*Tetranychus urticae*)	

SPEAR-LEP

Proposed use claim	Use pattern
Apple and Pear **Control of** Tortricid Moths (Codling Moth, Obliquebanded Leafroller, Oriental Fruit Moth, Tufted Apple Bud Moth)	Apply SPEAR-LEP at 1.2 - 2.3 L/ha in a tank mix with the low labelled rate of a *Bacillus thuringiensis* (Bt) product containing the subspecies *kurstaki* (Btk), such as Bioprotec, DiPel, Foray 48BA, ReVok^{BTK} and Thuricide-HPC and/or products containing the subspecies *aizawai* (Bta), such as XenTari. Repeat applications at 3- to 10-day-intervals depending upon plant growth rate, pest activity and other factors. Under heavy pest pressure conditions, use the shorter spray interval, the higher rate, and/or increase spray volume to improve spray
Peach **Control of** Oriental Fruit Moth	

Proposed use claim	Use pattern
Brassica Head and Stem Vegetables (Crop group 5-13); Brassica Leafy Greens (Crop subgroup 4-13B) **Control of** Cabbage Looper, Diamondback Moth, Imported Cabbageworm	coverage. Do not make more than three consecutive applications of SPEAR-LEP plus Bt and do not make more than six applications per year. Adjuvants may be used to achieve uniform plant coverage on plants that are difficult to wet, closed canopy or dense foliage. Use a spreader/sticker or non-ionic surfactant at 0.125% v/v to enhance the adhesion of SPEAR-LEP to the crop. Use a minimum of 187 L/ha for ground applications. Application timing and spray volumes recommended on Bt tank mix labels should be followed if more restrictive.
Celery, Tomato, Lettuce, Spinach **Control of** Beet Armyworm, Cabbage Looper	
Cranberry Control of Green Spanworm	

References

A. List of studies/Information submitted by registrant

1.0 Chemistry

PMRA document number	Reference
3237246	2021, Response to Notice of Deficiencies for VST-006325 Technical (new name VST-006335 MP), Sub. No. 2020-1192, DACO: 2.11, 2.12, 2.14, 2.3.1, 2.4, M2.10.1, M2.10.2, M2.5, M2.7 CBI
3237243	2020, Revised Manufacturing Process for VST-006335 MP, DACO: 2.11.1,2.11.2,2.11.3 CBI
3237242	2021, Determination of the Preliminary Analysis (5-batch Analysis) of GS-omega/kappa-Hxtx-Hv1a in VST-006335 Biological Insecticide End-Use Products by LC/UV, DACO: 2.11,2.12,2.3.1,2.4 CBI
3237241	2021, Discussion of Formation of Unintentional Ingredients for VST-006335 MP, DACO: 2.11,2.12,2.3.1,2.4,M2.10.2 CBI
3237240	2012, American Type Culture Collection (ATCC) deposition, DACO: M2.5 CBI
3237239	2018, Microbial Commercial Activity Notice (MCAN): Contained Use of a Genetically Engineered Yeast to Produce an Agricultural Product, DACO: M2.7.3.1, M2.7.3.2, M2.7.3.3, M2.7.3.4 CBI
3237238	2021, Analysis for Microbial Contaminants from [CBI removed] DACO: M2.10.1, M2.10.2 CBI
3105724	2020, 2.1,2.14, Product Identity, Manufacturing Process, Discussion of Formation of Unintentional Ingredients, Analysis of Samples, Certification of Limits, and Physical and Chemical Properties - Study Profile, DACO: 12.7.2, 2.1, 2.10, 2.2, 2.3.1, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, Document J, Document M, M2.1, M2.2, M2.3, M2.4, M2.5, M2.6 CBI
3105707	2012, Review of development and identity of VST-006325 TGAI, DACO: 10.2.1, 2.10, 2.11.3, 2.11.4, 2.14.14, 2.16, 4.1, M2.7.1, M2.7.2, M2.7.3, M2.7.3.1, M2.7.3.2, M2.7.3.3, M2.7.3.4 CBI
3105704	2020, 5 Batch Analysis of Spear Bulk Solution, DACO: 2.13.1,2.13.2,2.13.3,2.13.4 CBI
3255068	2021, Final Report for Determination of Color, Odor, Density, Stability to Metal Ions, Physical State, pH, UV/Visible Absorption, Vapor Pressure, and Viscosity of VST-6335 Biological Insecticides, DACO: 2.14.1, 2.14.12, 2.14.13, 2.14.15, 2.14.2, 2.14.3, 2.14.6, 2.14.9, 830.7000 CBI
3255067	2021, Analysis of Microbial Contamination, DACO: M2.10.2 CBI
3105702	2012, VST-006325: Physical and Chemical Characteristics: Color, Physical State, Odor, pH, Viscosity, and Density/Relative Density, DACO: 2.14.1, 2.14.15, 2.14.2, 2.14.3, 2.14.6, 830.7000

PMRA document number	Reference
3105701	2013, Validation of Bioactivity of VST-006325 TGAI Lot 1234603, DACO: 2.14.13, 2.14.14
3105700	2020, Solubility, DACO: 2.14.7,2.14.8
3105699	2017, Product Chemistry and Composition for VST-006335 MP, DACO: 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12.1, 2.13.1, 2.13.2, 2.13.3, 2.13.4, 2.14.12, 2.14.13, 2.3, 2.3.1, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9 CBI
3105698	2012, Product Chemistry and Composition for VST-006325 MP, DACO: 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12.1, 2.13.1, 2.13.2, 2.13.3, 2.13.4, 2.14.12, 2.14.13, 2.3, 2.3.1, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9 CBI
3105674	2012, Evaluation of Vestaron Samples for the Detection of Foodborne Pathogens, DACO: M2.10.2,M2.10.3,M2.9.3 CBI
3105673	2012, Evaluation of Vestaron Samples for the Detection of *Vibrio cholera*, DACO: M2.10.2,M2.9.3 CBI
3105867	2020, Additional Product Chemistry for SPEAR-LEP and SPEAR T, DACO: 3.1.1, 3.1.2, 3.1.3, 3.1.4, 3.5.12, 3.5.15, 3.5.4, 3.5.5, 3.5.8
3105869	2017, Product Chemistry for VST-006340 LC, DACO: 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.5.11, 3.5.13, 3.7 CBI
3105870	2017, Manufacturing Process for VST-006340 LC, DACO: 3.2.1, 3.2.2, 3.2.3, 3.3.1, 3.4.1, 3.7, M2.10.1, M2.10.2, M2.10.3, M2.8, M2.9.1, M2.9.2, M2.9.3 CBI
3105871	2020, VST-006300: A.I. and BIT Determination by HPLC with Caffeine Internal Standard, DACO: 3.4.1,3.4.2
3105873	2016, VST-006340 LC: Physical and Chemical Characteristics: Color, Physical State, Odor, pH, Viscosity, and Density, DACO: 3.5.1,3.5.2,3.5.3,3.5.6,3.5.7,3.5.9
3105874	2019, Determination of Accelerated Storage Stability and Corrosion Characteristics for GS-omega/kappa-Hxtx-Hv1a Bioinsecticide Liquid Concentrate (VST-006340 SL, VST-006340 LC), DACO: 3.5.10,3.5.14
3237681	2021, Deficiency response for SPEAR-LEP, Submission Number: 2020-1191 and SPEAR T, Submission Number: 2020-1193 , DACO: 3.1.3,3.1.4,3.2.1,3.2.2,3.4,3.5 CBI
3237683	2021, Determination of the Preliminary Analysis (5-batch Analysis) of GS-omega/kappa-Hxtx-Hv1a and BIT (benzisothiazolinone) in VST-006340 Biological Insecticide End-Use Products by LC/UV., DACO: 3.3.1,3.4.1 CBI
3271062	2021, Response to Deficiencies per the meeting between PMRA and Vestaron 31AUG2021, DACO: 3.5 CBI

2.0 Human and animal health

PMRA Document Number	Reference
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3105693	2011, VST-006325 Primary Skin Irritation Study in Rabbits, DACO: 4.2.5
3105694	2012, VST-006325 Primary Eye Irritation Study in Rabbits, DACO: 4.2.4
3105695	2012, VST-006325 Acute Inhalation Toxicity Study in Rats, DACO: 4.2.3
3105696	2011, VST-006325 Acute Dermal Toxicity Study in Rats, DACO: 4.2.2
3105697	2011, VST-006325 Acute Oral Toxicity Up And Down Procedure In Rats, DACO: 4.2.1
3105877	2017, VST-006340 LC: Acute Oral Toxicity- Up-And-Down Procedure in Rats, DACO: 4.6.1
3105878	2017, VST-006340 LC: Acute Dermal Toxicity in Rats, DACO: 4.6.2
3105879	2017, VST-006340 LC: Dermal Sensitization Test in Guinea Pigs - Buehler Method, DACO: 4.6.6
3286618	2021, VST-6300 (TGAI) A 90-Day Repeat Dose Oral Gavage Toxicity Study in Rats, DACO: 4.3.1
3286620	2021, VST-6300 (TGAI) Bacterial Reverse Mutation Test (Ames Test), DACO: 4.5.4
3286621	2020, In vitro Mammalian Chromosome Aberration Test in Chinese Hamster V79 Cells with VST-006300 TEP, DACO: 4.5.5
3298655	2020, VST-7300 (TGAI): A Developmental Toxicity Study In Pregnant Rats, DACO: 4.5.2,4.5.3,870.3700
3358963	2022, VST-6300 (TGAI): A Developmental Toxicity Study In Pregnant Rats, DACO: 4.5.2,4.5.3,870.3700
3105880	2020, Exposure (Occupational and/or Bystander) Summary for SPEAR T and SPEAR-LEP, DACO: 5.2

3.0 Environment

PMRA Document Number	Reference
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3105676	2012, VST-006325 Terrestrial Plant Toxicity, Vegetative Vigor, DACO: 9.8.4

PMRA Document Number	Reference
3105677	2020, Toxicity to Freshwater Alga or Estuarine or Marine Alga; Toxicity to Aquatic Vascular Plants, DACO: 9.8.2,9.8.3,9.8.4
3105678	2012, VST-006325 Acute Oral Toxicity Study in Bobwhite Quail, DACO: 9.6.2.1
3105679	2012, VST-006325 Rainbow Trout (*Oncorhynchus mykiss*) 96-Hour Acute Toxicity Test, DACO: 9.5.2.1
3105680	2012, VST-006325 Daphnia magna 48-Hour Acute Toxicity Test, DACO: 9.3.2
3105681	2015, Limit Test of VST-006330 EP on the Whitefly Parasitic Wasp *Eretmocerus eremicus* (Non-Target Organism) in a Translational Laboratory Study in North Carolina, DACO: 9.2.6
3105682	2015, Limit Test of VST-006330 EP on the Green Lacewing *Chrysoperla rubilabris* (Non-Target Organism) in a Translational Laboratory Study in North Carolina, DACO: 9.2.5
3105683	2015, Limit Test of VST-006330 EP on the Ladybird Beetle *Hippodamia convergens* (Non- Target Organism) in a Translational Laboratory Study in North Carolina, DACO: 9.2.5
3105684	2015, VST-006325 Technical: Honey Bee (*Apis mellifera* L.) Larval Toxicity Test (Single Feeding Exposure), DACO: 9.2.4.3
3105685	2013, GS-U-ACTX-HV1 a-SEQ2: An Acute Oral Toxicity Study with the Honey Bee, DACO: 9.2.4.2
3105686	2012, VST-006325 Honey Bee, *Apis mellifera*, Acute Contact Toxicity Limit Test, DACO: 9.2.4.1
3105707	2012, Review of development and identity of VST-006325 TGAI, DACO: 10.2.1, 2.10, 2.11.3, 2.11.4, 2.14.14, 2.16, 4.1, M2.7.1, M2.7.2, M2.7.3, M2.7.3.1, M2.7.3.2, M2.7.3.3, M2.7.3.4 CBI

4.0 Value

PMRA No.	Reference
3105755	2012, Review of development and identity of VST-006325 TGAI, DACO: 10.2.1,10.2.3.2(D),10.2.3.3(D)
3105757	2014, *Helicoverpa zea* - Certis @ 0.5 LB/A, DACO: 10.2.3.2(D)
3105758	2014, *Helicoverpa zea* - Certis @ 1.0 LB/A, DACO: 10.2.3.2(D)
3105759	2014, *Helicoverpa zea* - Certis @ 2.0 LB/A, DACO: 10.2.3.2(D)
3105760	2014, *S. exigua* - Certis @ 0.5 LB/A , DACO: 10.2.3.2(D)
3105762	2014, *S. exigua* - Certis @ 1.0 LB/A , DACO: 10.2.3.2(D)
3105763	2014, *S. exigua* - Certis @ 2.0 LB/A , DACO: 10.2.3.2(D)
3105764	2013, Vestaron Field to Lab Trial Beet Armyworm on Tomato 2013 , DACO: 10.2.3.2(D)
3105765	2013, Vestaron Field to Lab Trial with VST-006330 American Bollworm on Tomato 2013 , DACO: 10.2.3.2(D)

PMRA No.	Reference
3105768	2020, Spear peptide and Btk have a synergistic effect on lepidopteran larvae mortality, DACO: 10.2.1,10.2.3.2(D)
3105769	2017, US Patent toxic peptide production, peptide expression in plants and combinations of cysteine rich peptides, DACO: 10.2.1,10.2.3.2(D)
3105770	2018, Assessment study of the biological effectiveness of spear SL/spear T SL/Spear or SL/VST-006340 SL for the CONTROL of White midge (*Trialeurodes vaporariorum*) in tomato cultivation, DACO: 10.2.3.3(D)
3105771	2019, 2019 Blackberry SWD Control-SpearT , DACO: 10.2.3.3(D)
3105772	2019, Spear-T Greenhouse Trials, DACO: 10.2.3.3(D)
3105773	2019, Spear-T Greenhouse Trials, DACO: 10.2.3.3(D)
3105774	2019, Spear-T Greenhouse Trials, DACO: 10.2.3.3(D)
3105775	2019, Spear-T Greenhouse Trials, DACO: 10.2.3.3(D)
3105776	2019, Spear-T Greenhouse Trials, DACO: 10.2.3.3(D)
3105777	2019, Spear-T Greenhouse Trials, DACO: 10.2.3.3(D)
3105778	2019, Evaluate the efficacy of Spear-Lep against industry standards for control of Codling Moth, DACO: 10.2.3.3(D)
3105779	2019, Evaluate Spear Lep for Naval Orangeworm Control in Almonds Compared to a Grower Standard Treatment - WEN , DACO: 10.2.3.3(D)
3105780	2017, Vesteron products alone and in combination for control of lepidoptera pests on broccoli, DACO: 10.2.3.3(D)
3105786	2019, Evaluate use patterns of Spear Lep insecticide for the control of *Sparganothis* fruitworm in Wisconsin cranberries - 2019 - Adams 73 Marsh , DACO: 10.2.3.3(D)
3105787	2019, Evaluate use patterns of Spear Lep insecticide for the control of *Sparganothis* fruitworm in Wisconsin cranberries - 2019 - Arkdale Marsh , DACO: 10.2.3.3(D)
3105788	2019, Evaluate use patterns of Spear Lep insecticide for the control of *Sparganothis* fruitworm in Wisconsin cranberries - 2019 - Habelman Marsh , DACO: 10.2.3.3(D)
3105789	2019, Spear Lep on Lettuce, DACO: 10.2.3.3(D)
3105792	2018, Determine the residual efficacy of Spear Lep application for the control of diamondback moth DMB (*Plutella xylostella*) on cabbage, DACO: 10.2.3.3(D)
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3105797	2020, Summary Table of Spear-Lep Trials, DACO: 10.2.3.3(D)
3105798	2020, Summary Table of Spear-T Trials, DACO: 10.2.3.3(D)
3105799	2019, Evaluation of insecticide treatments in collards, 2019, DACO: 10.2.3.3(D)
3105800	2019, IsaGro/Spear-T/Onion, DACO: 10.2.3.3(D)
3105801	2019, CUCUMBER/MITES/SPEAR-T, DACO: 10.2.3.3(D)
3105802	2019, CUCUMBER/THRIPS/SPEAR-T , DACO: 10.2.3.3(D)
3105803	2019, MARIGOLD/MITES/SPEAR-T , DACO: 10.2.3.3(D)
3105804	2019, MARIGOLD/THRIPS/SPEAR-T, DACO: 10.2.3.3(D)

PMRA No.	Reference
3105805	2019, PEPPER/MITES/SPEAR-T , DACO: 10.2.3.3(D)
3105806	2019, TOMATO/MITES/SPEAR-T , DACO: 10.2.3.3(D)
3105807	2019, TOMATO/THRIPS/SPEAR-T , DACO: 10.2.3.3(D)
3105808	2019, Vestaron/Leps/Spear-lep/ , DACO: 10.2.3.3(D)
3105809	2019, Evaluation of Spear T (EP) to Control Whiteflies and Thrips in Greenhouse Ornamentals, DACO: 10.2.3.3(D)
3105810	2019, Efficacy of Spear-Lep in Apple , DACO: 10.2.3.3(D)
3105811	2019, Evaluated Spear-Lep insecticide use patterns for the control of blackheaded fireworms and spanworms in Wisconsin cranberries - Moodie Marsh - 2019 (Vestaron), DACO: 10.2.3.3(D)
3105812	2019, Evaluated Spear-Lep insecticide use patterns for the control of blackheaded fireworms and spanworms in Wisconsin cranberries - Potter Marsh - 2019 (Vestaron), DACO: 10.2.3.3(D)
3105813	John C. Wise, Anthony VanWoerkom, and Rufus Isaacs, 2016, Control of Spotted Wing Drosophila in Blueberries, 2016, Arthropod Management Tests, 2017, –2 DACO: 10.2.3.3(D)
3105814	2016, Spotted wing drosophila control in tart cherries, DACO: 10.2.3.3(D)
3105815	2017, Celery Chemical Screening Trials 2017, DACO: 10.2.3.3(D)
3105816	2018, Celery Chemical Screening Trials 2018, DACO: 10.2.3.3(D)
3105817	2019, Evaluate the efficacy of Spear-Lep on Apples, DACO: 10.2.3.3(D)
3105818	2018, To the determine efficacy of Spear T EP Compared to Spear T LC to Control Thrips and Whiteflies in Greenhouse Vegetables , DACO: 10.2.3.3(D)
3105819	2018, Evaluation of Spear T (EP) to control Thrips and Whitefly in Greenhouse Vegetables, DACO: 10.2.3.3(D)
3105821	2019, Evaluation of Spear-Lep against Lepidopteran pest affecting Cabbage Evaluation of Spear-Lep for Lepidopteran Pest Control in Cabbage, DACO: 10.2.3.3(D)
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3105832	2019, Efficacy of Spear-T Against Two Spotted Spider Mite Infesting Chrysanthemum under Greenhouse Conditions, DACO: 10.2.3.3(D)
3105833	2019, Efficacy of Spear-T Against Two Spotted Spider Mite Infesting Cucumber under Greenhouse Conditions, DACO: 10.2.3.3(D)
3105834	2019, Efficacy of Spear-T Against Two Spotted Spider Mite Infesting Geranium under Greenhouse Conditions, DACO: 10.2.3.3(D)

PMRA No.	Reference
3105835	2019, Efficacy of Spear-T Against Two Spotted Spider Mite Infesting Pepper under Greenhouse Conditions, DACO: 10.2.3.3(D)
3105836	2019, Efficacy of Spear-T Against Two Spotted Spider Mite Infesting Tomato under Greenhouse Conditions, DACO: 10.2.3.3(D)
3105837	2019, Efficacy of Spear-T Against Western Flower Thrips Infesting Chrysanthemum under Greenhouse Conditions, DACO: 10.2.3.3(D)
3105838	2019, Efficacy of Spear-T Against Western Flower Thrips Infesting Cucumber under Greenhouse Conditions, DACO: 10.2.3.3(D)
3105839	2019, Efficacy of Spear-T Against Western Flower Thrips Infesting Geranium under Greenhouse Conditions, DACO: 10.2.3.3(D)
3105840	2019, Efficacy of Spear-T Against Western Flower Thrips Infesting Pepper under Greenhouse Conditions, DACO: 10.2.3.3(D)
3105841	2019, Efficacy of Spear-T Against Western Flower Thrips Infesting Tomato under Greenhouse Conditions, DACO: 10.2.3.3(D)
3105842	2019, Efficacy of Spear-T Against Whitefly Infesting Chrysanthemum under Greenhouse Conditions, DACO: 10.2.3.3(D)
3105843	2019, Efficacy of Spear-T Against Whitefly Infesting Cucumber under Greenhouse Conditions, DACO: 10.2.3.3(D)
3105844	2019, Efficacy of Spear-T Against Whitefly Infesting Geranium under Greenhouse Conditions, DACO: 10.2.3.3(D)
3105845	2019, Efficacy of Spear-T Against Whitefly Infesting Pepper under Greenhouse Conditions, DACO: 10.2.3.3(D)
3105846	2019, Efficacy of Spear-T Against Whitefly Infesting Tomato under Greenhouse Conditions, DACO: 10.2.3.3(D)
3105847	2019, Exp. 1913 Efficacy of Spear-Lep against Summer Generation OBLR in Apple , DACO: 10.2.3.3(D)
3105849	2019, Spear-Lep in Cabbage, DACO: 10.2.3.3(D)
3105851	2019, Spear-Lep compared to CDY-X season long and in rotation with rate comparisons against internal and external LEPS., DACO: 10.2.3.3(D)
3105852	2019, SPEAR LEP 2.0: control of OFM in peach, DACO: 10.2.3.3(D)
3105853	2019, SPEAR LEP 2.0: control of PTB in young almonds, DACO: 10.2.3.3(D)
3105854	2019, Vestaron Spear-Lep for control of codling moth in pear. , DACO: 10.2.3.3(D)
3105855	2019, Efficacy of Spear-Lep against Pest in Apples, DACO: 10.2.3.3(D)
3105857	2020, Summary of Value for Spear T and Spear-Lep, containing GS-omega/kappa-Hxtx-Hv1a, for Control of Insects and Mites in Cannabis, Ornamentals, Fruits and Vegetables, DACO: 10.1, 10.2.1, 10.2.2, 10.2.3.1, 10.2.3.2(D), 10.2.3.3(D), 10.3.1, 10.3.2(B), 10.3.3, 10.4, 10.5.1, 10.5.2, 10.5.3, 10.5.4, 10.5.5
3192174	2019, 2019 Marrone Hemp Spider Mite, DACO: 10.2.3.3(D)
3192175	2020, 2020 Hemp Mite Vestaron, DACO: 10.2.3.3(D)

PMRA No.	Reference
3192176	2020, Exp. 12-20: Control of spotted wing drosophila in jersey blueberry, DACO: 10.2.3.3(D)
3192177	2020, 2020 Blackberry SWD Control (SpearT)-Vestaron Trial 1 , DACO: 10.2.3.3(D)
3192178	2020, 2020 Vestaron Blackberry SWD Control VST-202000- Trial 2 , DACO: 10.2.3.3(D)
3192179	2021, Deficiency Response for SPEAR-T, containing GS-omega/kappa-Hxtx-Hv1a, EP, Submission Number: 2020-1193, DACO: 10.2
3192198	2021, Deficiency Response for SPEAR-LEP, containing GS-omega/kappa-Hxtx-Hv1a, EP, Submission Number: 2020-1191, DACO: 10.2